DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 7, 2015

Valorem Surgical
% Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K140359
Trade/Device Name: MAXIMIS™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: December 9, 2014
Received: December 10, 2014

Dear Mr. Guthner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140359

Device Name
MAXIMIS™ Spinal Fixation System

Indications for Use *(Describe)*
The Valorem Surgical MAXIMIS™ Pedicle Screw Fixation System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: 1) trauma (i.e. fracture or dislocation), 2) curvatures (scoliosis, kyphosis, and/or lordosis) 3) spinal tumor, 4) failed previous fusion, 5) pseudoarthrosis, 6) spinal stenosis. It is not intended for pedicle screw fixation above T8. This device may be used with autograft of allograft.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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VALOREM SURGICAL
The Forefront of Innovation™

MAXIMIS™ Spinal Fixation System

510(k) SUMMARY

Traditional 510 (K) Premarket Notification: ***MAXIMIS ™ Spinal Fixation System***

1. Submitter/Sponsor:

Valorem Surgical
Joseph Jin, Executive Vice President
3963 West Belmont Ave., Chicago, Ill. 60618

Contact person:

Donald W. Guthner
Orgenix LLC
111 Hill Road
Douglassville, PA 19518
+1 646 460 2984 (office)
+1 484 363 5897 (FAX)
dg@orgenix.com

Date Prepared:

December 31, 2014

2. Device Name:

Classification Name:	Pedicle Screw Spinal System
Common/Generic Name:	Pedicle Screw Spinal System
Trade Name:	***MAXIMIS ™ Spinal Fixation System***

3. Device Classification(s):

Class II following Orthopedic and Rehabilitation Device Advisory Review, for the requested indications:

- Spinal Pedicle Screw (MNI) 21 CFR § 888.3070
- Spondylolisthesis Spinal Fixation Device System (MNH) 21 CFR § 888.3070

4. Predicate Device:

The technological characteristics (Material, design, sizing, Indications) of the subject device are similar to or identical to the citied predicate(s) within the body of this submission

5. Device Description:

The ***MAXIMIS ™*** **Spinal Fixation System** is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, and set screws. The ***MAXIMIS ™ Spinal Fixation System*** implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

The ***MAXIMIS ™ Spinal Fixation System*** can be used in the posterior plane providing bilateral modes of fixation.

The ***MAXIMIS ™ Spinal Fixation System*** design allows adjustment in both the sagittal

and coronal planes permitting screw placement according to the best possible anatomic (spinal) location and orientation.
This is accomplished by means of a mobile and non-mobile housing component which houses the screw and the rod which accepts a setscrew which tightens against the rod which tightens head of the pedicle screw upon secure tightening interface of the set screw assembly with the rod.
Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the ***MAXIMIS ™ Spinal Fixation System*** implants.
From the foregoing, we conclude that the subject ***MAXIMIS ™ Spinal Fixation System*** device is as safe and effective as named predicate and currently marketed competitive devices for the stated indications.

6. Indications for Use:
The Valorem Surgical **MAXIMIS™ Pedicle Screw Fixation System** is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: 1) trauma (i.e. fracture or dislocation), 2) curvatures (scoliosis, kyphosis, and/or lordosis) 3) spinal tumor, 4) failed previous fusion, 5) pseudoarthrosis, 6) spinal stenosis. It is not intended for pedicle screw fixation above T8. This device may be used with autograft of allograft.

7. Comparison with predicate device: The ***MAXIMIS ™ Spinal Fixation System*** is substantially equivalent to the Pallas M Spinal System (K120538), a currently marketed Spinal System. When considered for posterior applications, both the ***MAXIMIS ™ Spinal Fixation System*** and the named predicate worst case constructs consist of the same universal housing containing the same pre-assembled pedicle screw and set screw. Both systems use the same vertical rods which are both placed into the housing. The same set screws are subsequently tightened onto the rod, providing a completed implant assembly.

The principles of operation for the subject ***MAXIMIS ™ Spinal Fixation System*** device and the cited predicate technologies are the same. That is, each of these products employs the same indications for use, contraindications for use, warnings and precautions within labeling. The principles of operation of the subject device are directly equivalent to those of the cited predicates cleared by the Agency and currently being marketed.

The target populations on which product usage would occur for the subject device shall remain similar / equivalent to those of the cited predicate products.

(The term "Substantial Equivalence" is used only as it is defined in the Medical Device Amendment of 1976 as amended by the Safe Medical Device Act of 1990 and is not

intended to, nor does it refer to, the definition of substantial equivalence in the U.S. or any other patent law.)

The design and development process of the manufacturer of subject system and Predicate system conforms to 21 CFR part 820, ISO 9001 and ISO 13485 quality systems.

8. Performance Data The subject and predicate device were evaluated/tested per established requirements. The predicate device underwent mechanical testing included static and fatigue testing performed per:

- ASTM F1798-97: Standard guide for evaluation the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants
- ASTM F1717-04: Standard test methods for spinal implant constructs in a vertebrectomy model
- ASTM F2193-02: Standard specifications and test methods for components used in the surgical fixation of the spinal skeletal system

9. Clinical tests: No clinical tests were conducted on either the subject system or the predicate system.

10. Conclusion: The subject device was evaluated against the predicate device for all performance and found to be substantially equivalent to the predicate device.